"Lupin Limited Q1 FY2026 Earnings Conference Call"

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MANAGEMENT:

- **MS. VINITA GUPTA – CEO, LUPIN LIMITED**
- **MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**
- **MR. RAMESH SWAMINATHAN – EXECUTIVE DIRECTOR, GLOBAL CFO, HEAD OF IT AND API PLUS SBU, LUPIN LIMITED**
- **MR. RAVI AGRAWAL – INVESTOR RELATIONS AND M&A, LUPIN LIMITED**

Moderator: Welcome to Lupin Limited's Q1 FY26 Earnings Conference Call. I am Ravi Agrawal, Head of Investor Relations for Lupin. Thank you for your participation in the call today. Please note that all participants' line will be in listen-only mode, and there will be an opportunity for you to ask questions after the opening remarks. Please also note that this conference is being recorded.

I now hand over the conference to the management. Thank you, and over to you.

Vinita Gupta: Thank you, Ravi. I am very pleased to welcome you to our Q1 FY26 Earnings Call. I have with me here, Nilesh, our Managing Director; and our CFO, Ramesh; and of course, Ravi online as well. We look forward to sharing with you our highlights for the quarter, as well as outlook for the year ahead.

We are delighted to begin the fiscal year on a very strong note, with continued double-digit growth in both revenues and profitability. Our margins have shown further improvement, rising by 330 basis points YoY, even as we increased investment in R&D by 151 basis points during the same period.

Looking ahead, we are confident that this growth momentum will continue and reaffirm our EBITDA margin outlook for the fiscal year at 24% to 25%.

The first quarter marked a significant milestone for our U.S. business. We successfully launched Tolvaptan with sole first to file exclusivity, resulting in our highest U.S. revenues since Q4 FY2017 when we had the Glumetza® and Fortamet® franchise, and this is despite additional generic competition in Albuterol. Our ability to seamlessly launch Tolvaptan through specialty distribution channels stands as a testament to the strong execution and commercial capabilities we have built in the U.S.

We are confident in our ability to sustain growth in the U.S. market in the mid to long term with a strong pipeline across complex product categories, such as injectables, respiratory, biosimilars and 505(b)(2) products, targeting brand sales of USD 150 billion. We expect complex products to drive a significant portion of our growth and future business. Additionally, we remain focused on expanding our specialty business, both organically and inorganically.

Coming to India region, we reported growth of 7.8% YoY. Within this, our India Formulations business recorded growth of 8.6% during the quarter, in line with IPM growth. While key therapies like Cardiac, GI and VMS grew ahead of the market, and we have also increased our chronic share from 64% last year to 65% this quarter, LOE on certain in-licensed brands in the Diabetes segment have had a negative impact on our growth rates.

I'm particularly heartened by our Respiratory franchise performance, which grew 18.5% as against a category growth of 12.2% during the quarter. Also on MAT basis, the volume growth has been 2.8%, double the volume growth in IPM during this period.

During the quarter, we successfully completed the transfer of our OTC consumer healthcare business into a 100% owned subsidiary called LupinLife Consumer Healthcare. We believe that this separation will allow the OTC

business strategic flexibility to capitalize on the rapidly growing OTC market in India, while enabling the company to sharpen its focus on core strengths in the prescription drugs business.

We are confident that our India Formulations business will continue to outperform the market, propelled by our extensive portfolio of innovative and in-licensed products as well as the broad reach of our 10,000 plus people sales force. The introduction of new products will be pivotal to our growth with more than 80 product launches planned over the next five years.

As a major player in the Cardiac and Diabetes segment, GLP-1 products will remain a core part of our India strategy over the next couple of years. In addition, we are deepening our presence in GI, aiming to establish this as our fourth major therapy area. We are also focused on expanding our presence in Oncology and CNS segments going ahead.

Turning to Other Developed Markets, we achieved a 17% YoY increase, with Europe serving as a key growth driver, recording an impressive 28% increase for the quarter. These markets now account for 13% of our total sales, up from 11% two years ago. Looking ahead, we remain optimistic about sustaining this momentum, led by a robust pipeline of complex and specialty products going ahead.

Our R&D expenses as a percentage of sales stood at 7.9% for the quarter. We are especially encouraged by our recent FDA approvals for generic Victoza® and Glucagon, which highlight the progress we are making in complex injectables. We take pride in being the first Indian company to secure approval of a GLP-1 product for the U.S. market.

Nearly 70% of our R&D investments are directed towards complex and specialty products. We have a robust pipeline with over 60 product filings planned for the U.S, market alone in the coming years.

Our position in Inhalation is expanding rapidly, not just in the U.S, but also across India, Europe, and other international markets. In the complex injectables space, our focus is on developing depot injectables, peptides, iron colloid products, as well as 505(b)(2)s. We have also established a strong model in biosimilars outside the United States and are well positioned to enter the market in the U.S.

On the specialty side, we are advancing a substantial 505(b)(2) pipeline and enhancing our portfolio with value-added medicines, such as long-acting injectables, oral solids, IUD implants, and green propellant-based products. These initiatives will require increased investment, as we have indicated previously, and we anticipate R&D spend to be between 7.5% to 8.5% level in FY26.

On the compliance front during the quarter, our Nagpur Unit-2 site received its EIR, while there were some observations in the 483 issued for Pithampur Unit-2 and Unit-3 sites. We are confident of addressing the observations effectively and would like to reiterate that we are committed to ensure that

all our sites are fully compliant with the FDA and other regulatory agencies around the world.

Before I hand it over to Ramesh for a more detailed performance analysis, I want to reiterate our optimism regarding our future growth trajectory. The recent approvals for generic Victoza® and Glucagon, and the expected approval of generic Risperdal Consta® mark the beginning of our journey in complex injectables space, which will further strengthen our complex portfolio in the U.S.

Looking ahead to FY27, we expect to bolster our momentum with key launches from our biosimilars pipeline in the U.S as well. Our ongoing commitment is to build a leading global specialty business, leveraging both in-house innovation and strategic acquisitions. We are confident that our focused investments in R&D, patient-centric approach to building specialty brands, and continued efforts in driving efficiencies will drive sustainable growth in the years ahead.

With this, I will hand it over to Ramesh.

Ramesh Swaminathan: Thank you, Vinita. Friends, I welcome you all to our Q1 FY26 earnings call. This has been yet another quarter of consecutive double-digit growth across the top line and profits. I am particularly pleased to highlight that EBITDA margins have expanded by 330 basis points YoY to 26.6% during the quarter, despite 151 basis points increase in R&D during this period.

Diving into the numbers.

Sales

Sales for Q1 FY26 came in at INR 6,164 crores as compared to INR 5,514 crores in Q1 last year, a growth of 11.8% YoY. Amongst the key markets, the U.S grew by 24.3% YoY, India region has grown 7.8%, and Other Developed markets have grown 17.4% during the quarter. Our GIB business grew by 16% YoY.

US Business

In the quarter, the U.S business recorded sales of USD 282 million, a growth of 22.3% YoY and 12.8% QoQ on a constant currency basis.

As Vinita mentioned, this quarter was a pivotal one for the U.S, the successful launch of Tolvaptan, with sole FTF exclusivity. This was offset by low generic single-digit price decline in our base products and anticipated impact of new generic competition in Albuterol. We are continuing to execute on our strategy to improve our profitability in this segment, with yet another quarter of strong profitability from this business.

On the longer term, we remain confident of consistent delivery of profitable growth through an increasing share of complex products in our portfolio.

India

The India region business grew by 7.8% YoY during the quarter. Within this, the prescription business grew by 8.6% YoY during Q1 FY26, in line with IPM growth. Chronic share during the period was higher at 65% with key segments like Cardiovascular, GI, and VMS growing ahead of the IPM growth. The share of in-licensed products is only around 6.2% as compared to around 12% in FY25, which also has a positive impact on our profitability going ahead.

Other Developed Markets

So far as Other Developed Markets are concerned, revenues in our other developed markets were INR 775 crores, representing a growth of 17% YoY. This growth was led by 28% YoY increase in Europe.

Other Emerging Markets

Other Emerging Markets grew by 5.2%, with strong growth in South Africa offsetting tempered performance in LATAM and Philippines.

Coming to various aspects of the P&L.

Other Operating Income

Other Operating Income at INR 105 crores has increased by INR 18 crores as compared to the first quarter of FY25.

Gross Margins

Coming to the profitability, Gross Margins continued their upward trajectory with Q1 FY26 Gross Margins at 71.3%, up from 68.4% in Q1 last year, and up from 69.7% in Q4 FY25. This 290-basis points YoY improvement is driven by multiple factors, which includes better product mix, tailwinds on the input cost front, lower share of in-licensed products, increased volumes, and other cost improvements and efficiencies which we have undertaken over the last several quarters.

Employee Benefit Expenses

Employee benefit expenses at INR 1,083 crores increased 11.5% YoY from INR 971 crores in Q1 FY25, translating to 17.6% of sales, similar to Q1 last year. This change is largely attributable to higher costs due to regular annual increments and business growth during this period.

Manufacturing & Other Expenses

Q1 FY26 Manufacturing and Other expenses came in at INR 1,772 crores, increasing 10.9% YoY from INR 1,598 crores in Q1 FY25 and INR 1,688 crores in Q4 FY25, translating to 28.7% of sales versus 29% last year. The expenses are mainly higher due to higher R&D costs and higher volumes in the normal course of business.

R&D

R&D is at INR 484 crores at 7.9% of sales, as compared to INR 350 crores, which is 6.3% of sales in Q1 FY25, with almost 70% of our R&D directed towards complex portfolio. For the full year, as earlier indicated, we expect R&D to be about 8.5%.

EBITDA

Excluding Forex and other income, EBITDA was INR 1,641 crores vis-a-vis INR 1,286 crores in the same period last year, an increase of 27.6% YoY, with a margin of 26.6% versus 23.3% last year in the same period. On a QoQ, margins have expanded by 340 basis points. This margin expansion is on the backdrop of higher gross margins and a lower fixed cost during the period despite a higher R&D.

As previously guided, we expect full-year EBITDA margins to be in the range of 24% to 25%. Whilst we expect business to continue to exhibit robust performance, overall margins will be tempered by higher R&D spends and lower PLI in FY26 vis-a-vis FY25.

ETR

So far as the ETR is concerned, it was 13.7% for this quarter. However, for the full year, we expect the ETR to be around 19%.

Operating Working Capital

As far as the balance sheet is concerned, we are still working on operating working capital, which is of course standing at INR 7,287 crores as of 30 June against INR 6,821 crores as of 31 March 2025, which translates to 106 days of working capital against 110 days in the previous quarter.

Net Cash

Net cash at INR 1,239 crores as against INR 310 crores on 31 March 2025. Whilst we focus on increased cash generation for our business, we would like to highlight that we continue to explore strategic allocation of our capital to address the long-term vision of the company.

ESG

On the ESG front, we are pleased to report continued progress in Lupin's Environmental, Social and Governance performance, as demonstrated by our sustainability ESG ratings. This exposure has notably improved from a classification of "Severe Risk" in 2019 to "Medium Risk" in 2025. Additionally, with the Lupin Foundation, we have positively impacted lives of 22,400 individuals by enhancing access to healthcare and promoting livelihood opportunities.

With this, we open the floor for discussions.

Moderator: Thank you very much. We will now begin the question-and-answer session. Request that all participants who wish to ask questions to raise your hands on

the Participant tab on the screen. We will wait for 30 seconds for the queue to assemble.

The first question is from Kunal Dhamesha.

Kunal Dhamesha: First question on the top-line growth outlook. I think we have provided outlook on R&D, EBITDA margin. But if you could also provide our expectation for the overall top-line and as well as U.S. and, a related question is, Tolvaptan contribution in Q1 FY26, whether it was a partial contribution or a full quarter contribution?

Vinita Gupta: So top-line growth for the year, as we have guided earlier, we expect strong double-digit, both for the company and for the U.S. We launched Tolvaptan in late May. So, it was partial quarter. Since it's a specialty product, there was not too much of channel stocking ahead of the launch.

Kunal Dhamesha: And second one on the India business. The overall India business growth seems to be lower than our formulation business. So has the adjacency which is a small part of the business, has that kind of impacted, or there was a tender business last year that has impacted the growth? How should we think about it?

Nilesh Gupta: It's primarily the tender business, it's the institution business, which has impacted. And as we've discussed before, that's lumpy. But by and large, I think we're in a good place on the Global Institution Business as well.

Kunal Dhamesha: What would be the current drag from the adjacency business like diagnostics, etc., in this quarter particularly?

Ramesh Swaminathan: So, the impact on our EBITDA would be close to about 1%. They are still evolving and coming up very nicely. So, the long term obviously looks very alluring to us. But clearly, they're still loss-making at this stage.

Moderator: Next question is from Vivek from Citi.

Vivek Agrawal: Can you help us understand how to look the U.S. sales in FY27? In FY26, it is going to be good because you launched Tolvaptan, etc. But in FY27, there may be a cliff, as products like Tolvaptan, Mirabegron, etc., that may not be as big as they are in FY26. So how to look overall sales in FY27, especially for the U.S? What are the specific products, if you would like to highlight, that can help you mitigate the impact of decline in these products?

Vinita Gupta: So, there are many moving parts right now, I mean, on also material products like Tolvaptan as well as Mirabegron. Right now, there are no other tentative approvals on Tolvaptan, and it's a specialty product that requires a Named Patient REMS program, so we expect a substitution to be very different compared to a simple oral solid generic. That's number one.

Two, with Mirabegron, depending on the outcome on litigation as well as the trial of some of our competitors later this year, there are multiple scenarios that can emerge. So, we should have better clarity about that more at the end of this fiscal year, certainly in the second half of the fiscal year, we should have better clarity on the competition for products like Mirabegron.

Third, I would say that we have a number of new growth drivers. We are very excited with the build-up of our injectable pipeline portfolio with the approvals of significant products like Glucagon and Liraglutide. We have a goal date for Risperdal Consta® in September.

So, hopefully, the quarter after that, we launch our Gx Risperdal Consta®. So, the injectables start becoming a growth driver for us at the second half of this fiscal year, building into FY27.

And fourth, I would say that biosimilars is starting to look pretty promising as an opportunity, just given where things are in terms of access to market in the U.S. From our perspective, we have Pegfilgrastim that we will hope to receive approval for this year. We are making good progress on the OBI Pegfilgrastim. So, we would expect that, hopefully, to be filed and also get approved in FY 27 or FY 28. And FY 27, we expect in June '26, we have the goal date for Ranibizumab that we filed a few months ago. We expect both OBI as well as Ranibizumab to potentially come to market in FY27, building into FY28 as well.

So, while in some of the exclusive products, we will have additional competition impact, we think that some of the products are stickier than others. We remain very optimistic about growth prospects. Certainly, for the company overall, we expect a high single-digit growth for the next fiscal year, and hopefully double-digit as well based on the efforts our team has undertaken.

Ramesh Swaminathan: And I'll just add, perhaps there might be some volatility amongst quarters, but one is playing for the long term, and clearly, you see secular growth over an extended period of time, given our focus on a number of differentiated products, 505(b)(2)s.

Vivek Agrawal: So, in FY27, you are aspiring to be like a high single-digit-plus growth on FY26?

Ramesh Swaminathan: For the company as a whole.

Vivek Agrawal: Just one clarity on Pegfilgrastim On Body Injectors. So, have you filed or yet to file this product? Which product that you are expecting first? The normal Pegfilgrastim or the OBI one?

Nilesh Gupta: I am interested primarily in the OBI. Although the Pegfilgrastim approval will come sooner, we hope to file this during this fiscal year.

Vivek Agrawal: One question on the cost front, last year the company saved close to USD 50 million, so it would be great if you can highlight what are the targets for next couple of years, especially in the areas where the company is working on as far as the cost structure. I am trying to understand, margins for the FY27. For FY27, you have guided 24% - 25%. But is it possible that margins in FY27 can dip on the base of FY26, or you can still maintain margins in FY27 on the base of FY26?

Ramesh Swaminathan: The fact is we are playing for continuous margin expansion. This is on the back of, in fact, buoyancy on the top line, and we did indicate that next year also we would grow at least single digit numbers. But the focus on various items

of cost is incessant, and you would appreciate, the evidence is there to see. That will kind of provide for margin expansion going forward as well, despite, in fact, the kind of increases that we are seeing on the R&D front. So, we're pretty optimistic about this.

Moderator: The next question is from Saion Mukherjee of Nomura.

Saion Mukherjee: One question is on this whole tariff scenario. We may see an announcement in the near term. How are you assessing that? Any colour you can provide given the kind of products that you have or other mitigating measures that can be put in place? Basically, broadly trying to understand how you see the impact, let's say, if you have 10% or 15% kind of tariff being put on generic pharmaceuticals?

Vinita Gupta: It is of course hard to predict where this lands based on the outcome of the 232 investigations.

But I'd say that from a mitigating standpoint, the strategies that we have considered is, one - wherever we can, where we have price flexibility, price increase to offset the impact of tariff.

Number two - products where we have the ability to tech transfer into the U.S., certainly in the two sites, both New Jersey as well as Coral Springs. We are looking at a potential to transfer those products.

We are also considering some IP transfers that of course will have a capital gains impact, but overall will really benefit us, especially on high value products where we transfer the IP to the U.S and contract manufacture in India.

So, a combination of all of those measures, we expect to be able to mitigate a good percentage of the impact of tariffs. If it is 10%, 15%, I think it should be fairly manageable in any case. I mean, the question is, is it 25% or the 150% to 200% kind of numbers that have been floated.

Ramesh Swaminathan: And we should remember, at the end of the day, generics is all about access to medicines, so far as the population is concerned. So, they would also be very conscious of whatever measures that they take so it doesn't impact them too much considering the availability of products in recent times.

Saion Mukherjee: And the second question is on specialty. You are thinking about it for a while now. Given the changes that we are seeing in the U.S, particularly with respect to the pricing environment, is that changing your thought process around how you should be thinking about going about building the specialty business globally and in the U.S, in particular?

Vinita Gupta: Strategically, our focus has really been in niche therapy areas where we can really add value. So, areas like respiratory, and niche respiratory products or products that are not large in Asthma-COPD where we compete with big pharma. Plus, rare neurology products like NaMuscla®, we're actively developing NaMuscla® for the U.S, as well as other geographies, Europe included. So, we expect that the impact of MFN and all of the price reduction measures is likely going to have more of an implication for the large value

categories, where there is material spend from a government standpoint and a payer standpoint. Given our strategy is more on niche products, we believe that we will be in a better position than large brand companies in any case.

Saion Mukherjee: On NaMuscla®, if you can update us on the timeline for the U.S, and the market opportunity?

Vinita Gupta: We are in active recruitment right now for a Phase 3 study for U.S and Europe. We expect that the product will launch in the U.S in FY29. We believe that there's a market opportunity between USD 100 million to USD 200 million.

Moderator: The next question is from Kunal Randeria of Axis.

Kunal Randeria: Any update on Semaglutide filing plans in Canada?

Vinita Gupta: No, I think, from a near-term perspective, for the markets that open, we really have a partnered model. We have a partnership in place that will get us into the market. But internal injectable filing is a little bit later, due to the hurdle patent in the U.S. and other major markets.

Kunal Randeria: I meant Canada. Semaglutide in Canada?

Nilesh Gupta: So that will come through partnered, like Vinita said.

Kunal Randeria: Just to clarify on Mirabegron patent litigation. There are, I think, two patents under active litigation, right? And in one of the patents, I think the outcome depends on one of the other competitors, how their litigation goes. So, is there a likelihood of this drug facing competition by November itself?

Vinita Gupta: I would say it's really hard to predict. And anybody who is going through litigation in fall this year also has potentially looking at the timeline of our February trial, which is going to be material for the product.

Moderator: The next question is from Damayanti Kerai of HSBC.

Damayanti Kerai: So, my question is on your injectable portfolio build-up. So, first, have you launched Glucagon and Liraglutide in the U.S.? Are these products completely in-house, or you are engaging with some partners as well?

Vinita Gupta: So, we have launched Glucagon yesterday and plan to launch Liraglutide by October, and we manufacture the products in-house in Nagpur.

Damayanti Kerai: So, why are we waiting until next few months for Liraglutide launch?

Vinita Gupta: That's the time it takes to really do the validation and get launch quantities together.

Damayanti Kerai: And how do you see Liraglutide market in the U.S., given the market in general has moved to the new-generation therapies, your Semaglutide and Tirzepatide, etc.? Do you think this market is still attractive?

Vinita Gupta: We believe it is attractive because it's half a billion dollars plus, and there are very limited number of players right now. As the product gets more affordable with additional competition, we would expect that there is some share that

the product should take from the overall class. Definitely the portion that is price sensitive.

Damayanti Kerai: From sales build-up perspective, we should assume by FY27 that these two products are coming in FY26 and hopefully Risperdal Consta® also comes through. So, you have three key products in your portfolio to start with, and then assuming it will take a few months to build out, etc. So FY27 onwards we can assume these to be significant contributors in the U.S.

Vinita Gupta: That's right.

Damayanti Kerai: My next question is on your EBITDA margin. Ramesh, you mentioned there was some 1% drag due to adjacency in India. So similarly, can you quantify if there are other such drag on margins which are right now due to some investment or scale-up which are underway and then you expect these things to go away in few years or few quarters?

Ramesh Swaminathan: So, what I actually meant was that the adjacencies are costing us some monies because essentially, they are still evolving. Essentially, the digital business, the diagnostics business, the API CDMO business. There is time for them to evolve, they're all start-ups, so to speak. They would evolve to a size, to critical mass and they would start making profits. For example, the diagnostics business is expected to kind of breakeven next year. So that pathway has been very well set.

Damayanti Kerai: My next question is on your inhaler's portfolio. On Tiotropium, have you seen any meaningful market share than what we saw last quarter?

Vinita Gupta: It has been at a similar level.

Damayanti Kerai: So, what is actually stopping you to gain more market share? Or have you already reached the upper limit, and then we might not see market share gain from here? What are your thoughts on Tiotropium market share gain?

Vinita Gupta: The team is putting additional efforts around offsetting some of the cost to patients, especially in the Medicare - Medicaid covered patients. That is where we don't have a strong share. We have a really good share of the commercial covered patients, 50% plus. But the Medicare - Medicaid is where we are starting to see some benefits, but it's not showing in the numbers as of yet. But we hope that in the next couple of quarters that builds up.

Damayanti Kerai: So, going ahead, we might see more market share gain on the Medicaid - Medicare channel but on the commercial channel, you are broadly maybe at optimum level. Is that the way to look at this?

Vinita Gupta: Yes.

Moderator: The next question is from Neha Manpuria from Bank of America.

Neha Manpuria: My first question is on Tolvaptan. I think you had mentioned that based on contracts that we have in place, we should be able to get to about 25% market share on Tolvaptan. So, is that still the case? Or have you seen additional traction on the specialty contracts and that market share could be higher?

Vinita Gupta: So, it is hard to predict. I mean, right now, we've got good ramp up within the specialty channel. But it's still building. The conversion is still taking place. So, I think what you see is the impact of a couple of months of starting to build the share. But we should be able to see more of an impact in Q2 and Q3.

Neha Manpuria: So, the full contracted share will probably reflect exit of second quarter or third quarter. Would that be a fair assumption?

Vinita Gupta: Yes.

Neha Manpuria: Given that there is no tentative approval for Tolvaptan, is it fair to assume that we could probably have a longer tail for Tolvaptan versus a usual FTF product?

Vinita Gupta: We had estimated that we'll have additional competition in six months. But if we don't see it or if it's limited, one instead of two, perhaps there is more of an upside. And in any case, even with additional competition, we expect a longer tail given that it's a specialty product, it's the specialty channels, and the physicians don't like to change patients over and over again to a new product.

Neha Manpuria: My second question, Glucagon, while your press release mentions just the generic market, the IQVIA market for the generic and the brand, there are also 505(b)(2) in Glucagon. So, would it be fair to assume that our generic would be able to probably even look at that part of the market, the 505(b)(2)? Or you think it's just restricted to the generic products and the brand?

Vinita Gupta: So, we're targeting the entire market, but we'll know in the next couple of months how much of a share we can take of the whole market.

Moderator: The next question is from Shyam Srinivasan of Goldman Sachs.

Shyam Srinivasan: I think in the opening remarks; you talked about a potential new generic entrance on Albuterol? So, is there something that we need to worry? Also, from your competitive study or market study, how far away is other generics on, say, Spiriva perhaps?

Vinita Gupta: So Amphastar has entered the market on Albuterol. We've seen some impact of that you also see in the quarter that we had anticipated.

On Spiriva, you have couple of companies that have filed. But just given the time it takes and the source of supply of these companies, it's hard to say, companies like Alvogen and Teva, if they're going to get to the finish line on a timely basis. So, we hope it takes them as long as it took us, five years, to get approval.

Shyam Srinivasan: So, it is safe to assume another at least 12-18 months of like a runway for us?

Vinita Gupta: I would think so.

Shyam Srinivasan: Just a second question on biosimilars, since you have been starting to be more vocal, you have done an agreement with Zentiva. So, late entrant, especially in the U.S, not necessarily Europe. But U.S, do you see economics still reasonable, something that you will allocate additional capital to? In opening

remarks, you talked about on-body versus just the regular one. So, is there is some different entry strategy we might be doing as a follower, second wave? And how do we prepare for the 2029 kind of wave of the next biosimilars?

Vinita Gupta: So, I think while we are a late entrant, just given the market evolution, we may not be a late entrant. You're just seeing a substantial kind of easing on market access in the last 6-12 months, with Humira and the private labels that have come into market, like the Cordavis label, the Quallent label. They certainly have demonstrated the impact that some of the major customers can have with the private label strategy into the marketplace.

So, I'd say that from a capital allocation standpoint, we haven't shifted gears as of yet because we have a handful of products that are available to us already. We have, Pegfilgrastim, we have Onpro®. And we have interest both from partners as well as with a few of the oncology products that we have on a generic pipeline. Our commercial team is also looking at how we can leverage that to come to market direct.

Plus, on the ophthalmic front, given our ophthalmic portfolio, products like Ranibizumab, Aflibercept that come to market potentially in FY27 and FY28, can be good drivers of growth for biosimilars for us just given the limited number of competitors. Then, in FY29, we expect Etanercept. We're going to be likely one of four. That's still a material product, despite the price erosion that it has seen after IRA, or will see, based on the IRA negotiation. Still a significant product that we expect to benefit from.

Then we have a pipeline that we were pursuing. There is Certolizumab that we are developing. We are going to start development clinical development of Certolizumab soon. We have respiratory biosimilars, Mepolizumab and Benralizumab, that help us serve multiple markets, multiple geographies, not only the U.S, but also Europe, where we have a considerable position now with Luforbec®. In India, biosimilars are gaining momentum in our portfolio, especially of oncology and immuno-oncology products like Pembrolizumab and Nivolumab that we are developing for India.

So biosimilars is emerging as a platform that is going to have relevance for us in U.S, other developed markets like Europe, Canada, Australia, as well as India. So, a global platform that is really promising. We think that with the easing of the regulatory requirements from a clinical standpoint, as well as market access, it certainly will lead other companies also to accelerate their plans on the biosimilars front. So, we'll have to be mindful of the portfolio choices that we make. It will be like complex generics, we want to participate in products where we are in the first wave and we have barriers to entry, where we have exclusivity or semi-exclusivity, is what we're targeting, or we have a market position that we can leverage like Ophthalmics or Respiratory.

Moderator: We'll take the next question from Shashank Krishnakumar of Emkay.

Shashank Krishnakumar: My first one was on Dulera. Are we still on track for FY27 launch of this product in the U.S.?

Vinita Gupta: We're expecting to respond to the CRL in FY26. And hopefully, by the second half of FY27 or early FY28, we should be in the market with Dulera.

Shashank Krishnakumar: Second question was on the India business. I think in-licensing share obviously has come down to mid-single digits now. How do you sort of look at this going forward? Are we going to double down on our core business? Or will in-licensing still remain a key part of our domestic growth strategy in the medium term?

Nilesh Gupta: I think the focus on in-licensing remained all this while. But obviously with the LOE's and competition, that share has just been coming down. It's now down to 6% from a high of more than 20% at one point of time. The focus remains for example, even on GLP-1s, on other products, there is intent to in-license. There's a rich funnel. But the focus in the last three years, I would say, has been moving to focus on our own portfolio, including building our own novel portfolio as well. We are making good progress on that. I think that will remain the primary focus. Obviously, for the right kind of products, we would still want to in-license.

Shashank Krishnakumar: I think you mentioned about Phase 3 trials in the U.S. for NaMuscla®. But I think there has been a slight delay in Phase 3. So, is it largely a function of patient recruitment? Or has there been any other challenges there?

Vinita Gupta: No, it has been patient recruitment that has been slow. So, we are looking to open up some new centres as well.

Moderator: The next question is from Tushar Manudhane of Motilal.

Tushar Manudhane: Just on Liraglutide, while there is authorized generic as well as a couple of more approvals already, so how to think about this opportunity for Lupin?

Vinita Gupta: For us, strategically, one of our first few injectables, first product out of India. So, it starts creating a reputation for Lupin on the injectable front. And still a sizable product with a third entrant into the market potentially in October. We look at it as a sizable opportunity. Also, I'd add to that with Saxenda® potentially coming to market in the following year because they are very similar products, Victoza® and Saxenda®.

Tushar Manudhane: With respect to Risperdal Consta®, the goal date being September '25, is this to do with certain queries to be addressed, and which is where the timeline is September '25? If you can just elaborate on that as well.

Vinita Gupta: Yes. We had a couple of information requests based on which the goal date was moved to September, and we are responding to them, we have responded to them effectively. We believe we are on track for September.

Tushar Manudhane: So**,** a broad idea in terms of how many times or how many queries typically USFDA would sort of ask for such complex product before getting the final approval?

Vinita Gupta: It's hard to predict. I remember we had like looked at Tiotropium, we had like at the end 18 queries. But we are hoping that we are at the tail end with Risperdal Consta®.

Tushar Manudhane: Lastly on Tolvaptan. In the past, there has been certain tentative approvals. So, is it not going to be competitive post 180-day exclusivity?

Vinita Gupta: We haven't seen any tentative' s, so far.

Moderator: A follow-up question from Kunal Dhamesha of Macquarie.

Kunal Dhamesha: On the pricing comment, you said that it's a low single digit. There it is excluding Albuterol impact or including Albuterol impact?

Ramesh Swaminathan: Including.

Kunal Dhamesha: Secondly, on Tolvaptan, is it our own REMS? Or is it a shared REMS with the innovator?

Vinita Gupta: We don't want to share that. It's confidential.

Kunal Dhamesha: And then thirdly, in terms of Semaglutide Canada, has your partner's filing been accepted by the Canadian authority?

Vinita Gupta: No, it's still in the works. It hasn't been filed as of yet.

Kunal Dhamesha: And the last one on Dulera CRL, what is the nature? Is it to do with some clinical data or CMC queries or how should we think about that?

Nilesh Gupta: We do not want to talk about that.

Moderator: We'll take a follow-up question from Saion of Nomura.

Saion Mukherjee: Just a few product-specific questions. You had mentioned about a product called Dalbavancin some time back. Is this expected for launch this year?

Vinita Gupta: Yes.

Saion Mukherjee: And the other question is on GLP-1. If I heard you correctly, you said Victoza® generic in September, is that right, for the U.S.?

Vinita Gupta: **I** talked about generic Victoza® just got approved and will be launched in October. Risperdal Consta® will likely get approved in September.

Saion Mukherjee: And Saxenda® next year?

Vinita Gupta: Yes, next year.

Saion Mukherjee: So Saxenda you're expecting - just to clarify, Saxenda you're expecting this year approval, FY26?

Vinita Gupta: We are hoping that we get approved sooner rather than later. I mean, the goal date is into next year. But now that we've got the Victoza® product approval, we hope that the FDA is going to expedite.

Saion Mukherjee: Given that you're one of the few companies, which have been able to get an approval for a GLP-1 product, just from a regulatory standpoint, maybe for the U.S., of course, and for other markets, how do you see the hurdle from a regulatory approval perspective? Is there any takeaway for Semaglutide, or these are completely different products? And also, on Semaglutide, if you can

share your thoughts on India and the other markets and how excited you are about the opportunity next year.

Vinita Gupta: Yes, I think that it's fair to say Liraglutide was a complex product approval through the US FDA. The team really worked hard to respond to a number of pretty tricky queries and we believe that not everyone will get to the finish line. We think that the competitive dynamics there might be a little bit different than we had earlier expected.

Nilesh Gupta: I think what it does also is gives us a lot more capability. It gives our people a lot more confidence to be able to develop other products in the GLP-1 space. On Semaglutide, India, the injectable, we hope to be in the first wave. That will come through partnership. The oral solid is what we're developing internally. That will come a little later, hopefully in the next fiscal.

Saion Mukherjee: You mean FY27 you expect?

Nilesh Gupta: Yes, FY27 for the oral, end of FY26 for the injectable. We're a large metabolic player. So obviously, from that perspective, it's very interesting. There will be competition, but I think we should be able to get more than typical share.

Saion Mukherjee: And do you see the risk of delayed launch from a regulatory standpoint in India for the injectable?

Nilesh Gupta: So, nobody's got it yet, right? And it's under development across the board. So, I think there could be. But I think better than even chances of it coming through at that time.

Moderator: Since there are no further questions, I would hand it over to the management for closing comments.

Vinita Gupta: Thank you, Ravi. I hope we were able to respond to all your questions, number of questions on our portfolio, portfolio evolution, as well as growth prospects. I just want to reiterate that we are very optimistic that we continue our growth momentum this fiscal year as well as in the next couple of years despite the challenges on additional competition on key products. We believe that we have significant growth drivers in place. The team is very excited and energized to build on the success that we have built over the last couple of years and into this fiscal year as well.

So, look forward to continuing the momentum and connecting with you again over the next couple of quarters. Thank you.

Moderator: Thank you. On behalf of Lupin Limited, this concludes our conference. Thank you for joining us, and you may now exit the webinar.